NOV 21 2000 K002214/S1

510(k) Summary

Submitter's Information: **Date: 11/15/00**

Name: Pollux Endoscopy, Inc.
Contact: Precious J. Resch
Address: 2404 Airport Road, Suite #2
Plant City, FL 33567
Tel: (813) 719-7397
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Device Name:

Proprietary Name: Sinuscope
Common Name: Sinuscope
Classification Name: Sinuscope

Predicate Device Identification:

Corporation: Precision Optics Corporation
Predicate device: Sinuscope K983123

Substantial Equivalence

Pollux Endoscopy's Sinuscope is substantially equivalent to cited predicate device. The device is identical in external materials, construction, and fundamental operational procedures.

Intended Use: The sinuscope is intended to provide the physician with a means of endoscopic, diagnostic and therapeutic sinus surgical procedures.

Description: A rigid endoscope that is composed of medical grade stainless steel with an overrall length of 230mm. It has an internal optical system for conveying an image to the user's eye. The technological characteristics of the device is identical to the predicate device K983123.

Substantial Equivalence Comparison

Predicate Device: Sinuscope K983123

Table 2. Comparison of Materials

Sinuscope (Predicate Device)		Sinuscope (Pollux Endo)
Tubing	Stainless Steel Electro-polished	Stainless Steel Electro-polished
Fiber bundles	Hoya Schott	Hoya Schott
Body	Stainless Steel Electro-polished	Stainless Steel Electro-polished
Eyepiece	Delrin	P.E.E.K.
Light post	Stainless Steel Electro-polished	Stainless Steel Electro-polished

Table 3. Comparison of Optical Performance

Sinuscope (Predicate Device)		Sinuscope (Pollux Endo)
Field of View	95°	95°
Direction of Center of Field of view	0°	0°/ 30°/ 45°/ 70°
Depth of Field	5mm-40mm	5mm-40mm
Resolution	7.13 line pairs mm	7.13 line pairs mm

Table 4. Comparison of Dimensions

Sinuscope (Predicate Device)	**Sinuscope** (Pollux Endo)
Overall Length	
230mm	230mm
Diameter of Objective Lens	
2.78mm	1.8mm/2.78mm
Diameter of Eyepiece	
31.75mm	31.75mm
Maximum Diameter of Shaft	
4mm	2.7mm / 4mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

Mr. Precious J. Resch
Pollux Endoscopy, Inc.
2404 Airport Rd., Suite 2
Plant City, FL 33567

Re: K002214
Trade Name: Sinuscope and Accessories
Regulatory Class: II
Product Code: EOB
Dated: October 11, 2000
Received: October 17, 2000

Dear Mr. Resch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications for Use

Applicant: Pollux Endoscopy, Inc.

510(k) Number: K002214
Device Name: Sinuscope and Accessories

Indications for Use:

The Blazejewski Medi-Tech of Germany, sinuscope is intended to provide the physician with a means for endoscopic, diagnostic and therapeutic sinus surgical procedures.

The Sinuscope and accessories are indicated for use to examine and treat the nasal cavity and ~~nasal~~ naso pharynx by providing illumination and visualization of these regions.

The Sinuscope accessories will include sheaths to establish portals for visualization and surgical access and the suction/irrigation handle to remove debris and body fluids from the surgical site and to provide irrigation of the site with sterile solution of saline water.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off) JS
Division of Ophthalmic Devices
510(k) Number K002214

Enclosure 6